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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53 (c).

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☐ *Additional inventors are being named on the ____ separately numbered sheets attached hereto*

TITLE OF THE INVENTION (280 characters max)

CORONARY SINUS APPROACH FOR REPAIR OF MITRAL VALVE REGURGITATION

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ENCLOSED APPLICATION PARTS *(check all that apply)*

☒ Specification *Number of Pages* 21 ☐ CD(s), Number

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☐ Application Data Sheet. See 37 CFR 1.76

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT *(check one)*

☐ Applicant claims small entity status. See 37 CFR 1.27.

☐ A check or money order is enclosed to cover the filing fees — FILING FEE AMOUNT ($)

☒ The Commissioner is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number: 50-1713 — 160.00

☐ Payment by credit card. Form PTO-2038 is attached.

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

☒ No.

☐ Yes, the name of the U.S. Government agency and the Government contract number are: ____.

Respectfully submitted,

SIGNATURE [signature] Date 11/12/03

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TELEPHONE 847 905-7111 Docket Number: P1906 PRO (2650/195)

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

This collection of information is required by 37 CFR 1.51. The information is used by the public to file (and by the PTO to process) a provisional application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the complete provisional application to the PTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C., 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Box Provisional Application, Assistant Commissioner for Patents, Washington, D.C. 20231.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
APPLICATION FOR UNITED STATES LETTERS PATENT

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TITLE: CORONARY SINUS APPROACH FOR REPAIR OF MITRAL VALVE REGURGITATION

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CORONARY SINUS APPROACH FOR REPAIR OF MITRAL VALVE REGURGITATION

TECHNICAL FIELD

[0001] The technical field of this disclosure is medical devices, particularly for treating mitral valve regurgitation.

BACKGROUND OF THE INVENTION:

[0002] Valve insufficiency and regurgitation is a potentially grave health issue that can lead to cardiac dysfunction. Mitral valve insufficiency may comprise a valve that does not completely shut and affect the seal between the left ventricle and the left atrium. Historically, such a condition necessitated surgical intervention.

[0003] Surgical repair of mitral valve insufficiency historically involved the use of a sternotomy or a similar invasive procedure. After performing a sternotomy, the patient's heart would be stopped while the surgeon transected the chambers of the heart to gain access to the mitral valve. Upon attaining access to the mitral valve, the surgeon could then repair the valve by an annuloplasty, or suturing the valve. These procedures are complex, time consuming, and involve many risks attendant with open cardiac surgery. Complications may occur, and recovery time may be significant.

[0004] Tubular member based valve replacement has been proposed as a way to effect valve replacement percutaneously and to avoid open-heart surgery. Such procedures involve excision of the native valve and replacement of the native valve with a prosthetic valve, or installation of a prosthetic valve over the native valve, or a device to repair the damaged valve. Previous proposed treatments involve the use of clips to bind the posterior and anterior leaflets of the mitral valve. To avoid cardiopulmonary bypass, the tubular member based valve replacement is performed on a beating heart. Following excision of the native valve, no valve is present to preserve the

pumping action of the heart while the permanent prosthetic valve is being implanted.

[0005] An additional consideration in both open-heart and tubular member based valve replacement is the healing process after the prosthetic valve is implanted. After the surgical valve replacement procedure, scar tissue must form around the sewing cuff to secure the prosthetic valve in position. In current practice, multiple knotted sutures anchor the prosthetic valve in place until in-growth of scar tissue into the sewing cuff takes over the load bearing function. However, the placement of knotted sutures by tubular member can be very difficult and time consuming.

[0006] Artificial heart valves for temporary use are known in the art, but present certain problems. Some designs are complex, inflating and deflating balloons to alternately block and permit flow. Such designs require complex sensing and control systems. Other designs fail to provide access for tools that must reach the valve site for removal of the native valve and placement of the prosthetic valve. Yet other designs require elaborate supporting frames to hold the valve portion.

[0007] U.S. Patent No. 3,671,979 to Moulopoulos discloses an artificial heart valve for implantation in close proximity to a malfunctioning or damaged natural aortic or mitral heart valve by remote means without performing an open chest or other major surgical operation, the artificial heart valve comprising a flexible membrane in the form of an umbrella.

[0008] U.S. Patent No. 4,056,854 to Boretos et al. discloses an artificial valve remotely placeable in a blood vessel without major surgery to supplant the function of a malfunctioning natural valve including an expansible check valve remotely placed in a constricted configuration through the vessel and a remotely removable constraint for selective expansion of the check valve for sealing engagement thereof within the walls of the vessel at the desired location.

[0009] U.S. Patent No. 4,705,507 to Boyles discloses an arterial tubular member of the multi-lumen type having an inflatable balloon portion to wedge the tubular member in place against the arterial wall. Multi-infusions are

allowed through the segmented multi-lumens. The tubular member is designed to allow blood to flow in the arterial system with the tubular member in place. During diastolic phases, the blood flow will be closed off with movable plastic valves.

[00010] U.S. Patent Application No. 20020151970 to Garrison et al. discloses a valve implantation system having a valve displacer for displacing and holding the native valve leaflets open wherein a replacement valve may be attached to the valve displacer before or after introduction and may be positioned independent of the valve displacer and wherein a temporary valve mechanism may be used to provide temporary valve functions during and after deployment of the valve displacer.

[00011] WIPO International Publication No. WO 00/44313 to Lambrecht et al. discloses temporary valve devices with one or more cannulae which guide insertion of the valve into the aorta. The valve devices expand in the aorta to occupy the entire flow path of the vessel. In one embodiment, the temporary valve has leaflets that act in concert to alternately block or allow blood flow.

[00012] It would be desirable therefore to provide an apparatus and method that overcomes these, and other, problems.

SUMMARY OF THE INVENTION

[00013] One embodiment of the invention provides a system for treating cardiac valve regurgitation including a tubular member including a locking mechanism. An extendible member is carried on the tubular member, and the extendible member is movable to a deployment position responsive to application of an axial force. The extendible member is locked in the deployment position with the locking mechanism.

[00014] A second embodiment of the invention provides a system for treating cardiac valve regurgitation including a tubular member and an extendible member carried on the tubular member. A sleeve member including a slot

formed therein is positioned over the extendible member. The sleeve member is rotatable to align the slot with the extendible member.

[00015] Another embodiment of the invention provides a method for treating mitral valve regurgitation. The method includes positioning an extendible member adjacent a cardiac valve exterior to a heart chamber via a tubular member and applying an axial force to the extendible member. The extendible member is positioned in an extended position responsive to the axial force and locked in the extended position to apply a compressive force to the cardiac valve.

[00016] Yet another embodiment of the invention provides a method for treating mitral valve regurgitation. The method includes positioning an extendible member adjacent a cardiac valve exterior to a heart chamber via a tubular member and applying a rotational force to a sleeve member positioned on the extendible member. A slot of the sleeve member is aligned with the extendible member in response to the rotation and the extendible member is deployed through the slot and adjacent the cardiac valve.

[00017] The present invention is illustrated by the accompanying drawings of various embodiments and the detailed description given below. The drawings should not be taken to limit the invention to the specific embodiments, but are for explanation and understanding. The detailed description and drawings are merely illustrative of the invention rather than limiting, the scope of the invention being defined by the appended claims and equivalents thereof. The foregoing aspects and other attendant advantages of the present invention will become more readily appreciated by the detailed description taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE FIGURES

[00018] FIG. 1 illustrates a side view of one embodiment of a device used in accordance with the present invention prior to deployment;

[00019] FIG. 2 illustrates a side view of the device illustrated in FIG. 1 in a deployed position;

[00020] FIG. 3 illustrates a side view of the device illustrated in FIG. 1 in an alternate deployed position in accordance with another aspect of the invention;

[00021] FIG. 4 illustrates an embodiment of a device deployed within a coronary sinus adjacent a mitral valve in accordance with an aspect of the invention;

[00022] FIG. 5 illustrates a side view of an embodiment of a device prior to deployment in accordance with an aspect of the invention;

[00023] FIG. 6 illustrates a cross section of the device illustrated in FIG. 5 in accordance with an aspect of the invention;

[00024] FIG. 7 illustrates a side view of the device illustrated in FIG. 5 in a deployed position;

[00025] FIG. 8 illustrates a perspective view of the device illustrated in FIG. 5;

[00026] FIG. 9 is an illustration of a device in accordance with the present invention disposed in a coronary sinus prior to deployment adjacent a dilated mitral valve;

[00027] FIG. 10 is an illustration of a device in accordance with the present invention disposed in a coronary sinus after deployment adjacent a mitral valve;

[00028] FIG. 11 is a flowchart illustrating a method for treating cardiac valve regurgitation in accordance with one embodiment of the present invention;

[00029] FIG. 12 is a flowchart illustrating a method for treating cardiac valve regurgitation in accordance with one embodiment of the present invention;

[00030] FIG. 13 is a side view of a delivery device in accordance with another aspect of the invention;

[00031] FIGS. 14A and B are side views of a delivery device in accordance with another aspect of the invention; and

[00032] FIGS. 15A-C are side views of a delivery device in accordance with another aspect of the invention.

DETAILED DESCRIPTION OF THE PRESENTLY PREFERRED EMBODIMENTS

[00033] Referring to FIG. 1, one embodiment of a treatment system for cardiac valves is generally shown at numeral 10. In FIG. 1, the system is illustrated in a closed, non-deployed position. The treatment system includes an extendible member 120 coaxially carried upon a tubular member 110. The tubular member 110 includes at least one locking mechanism, the locking mechanism including at least one one-way protrusion lock member 140 and at least one stop member 150. The at least one lock member and the at least one stop member 150 are spaced apart along a length L of tubular member 110. The tubular member comprises a distal portion 180 and a proximal portion 190.

[00034] In one embodiment, extendible member 120 comprises a stent. In such embodiments, the stent may be either self-expanding or balloon expanding.

[00035] One-way protrusion lock member 140 (lock member) is a protrusion along a surface of the tubular member 110 that is configured to stop axial movement of the extendible member 120 from progressing beyond the lock member 140. In one embodiment, lock member 140 comprises ratchet teeth in a portion of a ratchet system. For example, the plurality of lock members 140 are configured to allow the extendible member 120 to move substantially freely from a proximal portion 190 to a distal portion 180, while preventing movement of the extendible member 120 from the distal position 180 to a proximal position 190.

[00036] Stop member 150 is a protrusion along a surface of the tubular member 110 that is configured to stop axial movement of the extendible member 120 from progressing beyond the stop member 150. In one embodiment, stop member 150 is a triangular protrusion configured with a perpendicular leg substantially perpendicular to the axis of the extendible

member 120, a parallel leg disposed parallel with the extendible member 120 and a hypotenuse leg disposed at an angle relative to both the perpendicular leg and the parallel leg. In another embodiment, stop member 150 comprises a stop ring. In another embodiment, stop member 150 comprises a frustoconical portion of the tubular member 110. In another embodiment, stop member 150 comprises a portion of the extendible member 120 that is affixed to the tubular member 110. In one embodiment, a distal portion 125 of extendible member 120 abuts stop member 150.

[00037] FIG. 2 illustrates the embodiment illustrated in FIG. 1 in a deployed position. As illustrated, FIG. 2 comprises the extendible member 120 axially carried upon the tubular member 110, with at least one one-way protrusion lock member 140 and at least one stop member 150. The tubular member 110 comprises a distal portion 180 and a proximal portion 190. FIG. 2 further illustrates that extendible member 120 assumes at least one deployment configuration 135. Deployment configuration 135 may be a single radially extended portion, or a plurality of radially extended portions. In one embodiment, axial compression of extendible member 120 actuates the deployment configuration 135 and interfaces with an interior wall of a coronary sinus. In another embodiment, the extendible member 120 comprises a self-expanding member having a predetermined deployment configuration to interface with an interior wall of a coronary sinus.

[00038] To deploy the system illustrated in FIGS. 1 and 2, the extendible member 120 slides along the tubular member 110 in response to an applied axial force. In one embodiment, the axial force is applied to the extendible member 120 to bias or push the extendible member to the distal portion 180. The extendible member 120 substantially freely slides over the lock member 140, which is in a ratchet lock configuration. If axial force remains applied against the extendible member 120, a deployment configuration 135 of the extendible member 120 forms. In one embodiment, the deployment configuration 135 creates a bowed shape, comprising a radiused portion and increasing the radial distance between the extendible member 120 and the

tubular member 110 over at least a portion of the length of the tubular member 110.

[00039] FIG. 3 illustrates another embodiment of the invention. In the embodiment illustrated in FIG. 3, deployment configuration 135 comprises a series of bowed shapes. In such an embodiment, the extendible member 120 comprises a shape memory material, such as: stainless steel, nitinol, tantalum, MP35N cobalt alloy, platinum, titanium, a thermoset plastic, a suitable biocompatible alloy, a suitable biocompatible material, or a combination thereof. The extendible member 120 is preshaped into the desired shape, and restrained from attaining the deployment configuration 135 until allowed to attain such shape in response to axial forces applied to the extendible member 120 between lock members 140 and stop members 150.

[00040] FIG. 4 illustrates one embodiment of the invention, deployed via a coronary sinus 175 to a position proximate a mitral valve 185. As shown in FIG. 4, the deployed extendible member 120 comprises a deployment configuration 135 and exerts pressure upon a wall 170 of the coronary sinus 175, in turn exerting pressure upon an annulus 195 of the mitral valve 185, and affecting the shape of the mitral valve 185. In one embodiment, the deployment configuration 135 comprises a bowed shape. In one embodiment, the deployment configuration 135 comprises a shape predetermined to interface with an inner wall of the coronary sinus. In another embodiment, the deployment configuration 135 is predetermined to reduce a natural curved shape of a coronary sinus by straightening the curve.

[00041] FIG. 5 illustrates another embodiment of a system in accordance with the invention. As illustrated in FIG. 5, the invention may also comprise a sleeve member 518 and an inner tube 528. As further illustrated in FIG. 5, sleeve member 518 comprises slot 538. Slot 538 is formed within the sleeve member 518. Sleeve member 518 is rotatably and slidably carried upon extendible member 528. Sleeve member 518 and inner tube 528 comprise materials that are sufficiently rigid to maintain their shape in response to axial and radial forces, while being sufficiently flexible to navigate the vasculature, and

sufficiently flexible to navigate a coronary sinus. Inner tube 528 is carried upon a catheter 503.

[00042] FIG. 6 is a cross-section view of the embodiment illustrated in FIG. 5, taken at line A-A. As illustrated in FIG. 6, the system includes sleeve member 518 and inner tube 528, as well as spring 612. Spring 612 is in a restrained position in FIG. 6, and is restrained by sleeve member 518. Spring 612 is any material capable of bias. In one embodiment, spring 612 is a flat spring. In another embodiment, spring 612 comprises a preshaped, shape-memory material, such as, for example, stainless steel, nitinol, tantalum, MP35N cobalt alloy, platinum, titanium, a thermoset plastic, a suitable biocompatible alloy, a suitable biocompatible material, or a combination thereof. In one embodiment, the deployment position interfaces with an interior wall of a coronary sinus. The sleeve member 518 is rotatable to align the slot 538 with the spring 612.

[00043] FIG. 7 illustrates a side view of the system illustrated in FIG. 5 with spring 612 distending through slot 538. To enable spring 612 to distend through slot 538, inner tube 528 is rotated with respect to sleeve member 518.

[00044] FIG. 8 illustrates a perspective view of the system, showing the inner tube 528, sleeve member 518, and slot 538.

[00045] Those of ordinary skill in the art will readily recognize that the system depicted in FIGS 5-8 can be readily modified to create multiple deployment configurations. Multiple deployment configurations may be created by varying the length of slot 538, and by varying the number of slots 538. Other modifications to the deployment configuration may be made by providing a stepped slot with varying widths or radii.

[00046] FIG. 9 is an illustration of the system depicted in FIG. 1 immediately prior to deployment. Mitral valve 185 is shown slightly open, indicating a condition amenable to mitral valve regurgitation. Coronary sinus 175 abuts the exterior of the heart proximate the mitral valve 185. Extendible member 120 and tubular member 110 are visible disposed within the coronary sinus 175.

[00047] FIG. 10 illustrates the system depicted in FIG. 2, deployed within a coronary sinus 175. As shown in FIG. 10, the mitral valve 185 is no longer slightly open, and is thus at reduced risk for mitral valve regurgitation. After deployment, deployment configuration 135 extends into a wall of the coronary sinus 175 and affects the shape of the coronary sinus. The altered wall of the coronary sinus then affects the annulus of the mitral valve 185, altering the shape of the mitral valve 185 and positioning the mitral valve to assume a proper fit and seal. The deployment configuration 135 applies a compressive force through the coronary sinus wall to the mitral valve annulus, altering the shape of the mitral valve.

[00048] FIG. 11 illustrates a method for treating mitral valve regurgitation in accordance with the instant invention. Method 1100 begins at Step S1110 when an extendible member is positioned within a vessel adjacent a cardiac valve exterior to a heart chamber via a catheter. In one embodiment, the extendible member is positioned within the coronary sinus adjacent the mitral valve. In one embodiment, the extendible member is carried upon the catheter.

[00049] At Step S1120, an axial force is applied to the extendible member.

[00050] At Step S1130, the extendible member is positioned in an extended position in response to the axial force. In one embodiment, the extendible member may assume extended positions over several positions of the extendible member. In other embodiments, the extended position is in a deployment position, and in other embodiments, a plurality of deployment positions are created along a length of the extendible member.

[00051] At Step S1140, the extendible member is locked in the extended position to apply a compressive force to the cardiac valve. In one embodiment, the extendible member is locked in an extended position within a coronary sinus and applies compressive forces to the mitral valve. In another embodiment, the extendible member applies a compressive force to the annulus of the mitral valve. Use of balloon expansion devices provides additional forces to the wall of the vessel and the affected cardiac valve, in one embodiment.

[00052] FIG. 12 illustrates an embodiment of a method for treating mitral valve regurgitation in accordance with the instant invention. Method 1200 starts at Step S1210 by positioning an extendible member adjacent a cardiac valve exterior to a heart chamber via a catheter. In one embodiment, the extendible member is positioned within the coronary sinus adjacent the mitral valve. In one embodiment, the extendible member is carried upon the catheter. The extendible member is disposed within a sleeve member comprising a slot, with the extendible member non-aligned with the slot.

[00053] At Step S1220, a rotational force is applied to a sleeve member positioned on the extendible member.

[00054] At Step S1230, the rotational force aligns the slot of the sleeve member with the extendible member. In one embodiment, the extendible member is a flat spring. In another embodiment, the extendible member comprises a preshaped shape memory material restrained from assuming the preshaped configuration by the non-alignment of the extendible member and the sleeve member.

[00055] At Step S1240, the extendible member deploys through the slot of the sleeve member responsive to the alignment. Deploying the extendible member results in the application of a compressive force against the cardiac valve. In one embodiment, deploying the extendible member results in application of a compressive force against a mitral valve.

[00056] In one embodiment, the surface of each component of the systems illustrated in FIGS 1-10 is treated with a substance to enable radiographic or magnetic imaging of the system during deployment. Accurate imaging of the device can ensure the system is delivered as intended by the health professional treating a cardiac valve. Substances to enable imaging of the system are known to those of ordinary skill in the art

[00057] The system of FIGS 1-10 is delivered through the vasculature of a patient. In one embodiment, the system is delivered with a catheter. Numerous approaches to deliver a catheter to a position within the coronary sinus are known to those of ordinary skill in the art.

[00058] The device illustrated in FIGS. 1-4 is delivered to the desired location, and the extendible member is to remain deployed at the delivery site after the end of the deployment procedure. FIG. 13 illustrates one embodiment of a delivery device 1310 in accordance with the invention. Delivery device 1310 comprises a delivery tube 1320, a pushing tube 1330 and a holding tube 1340. Holding tube 1340 is carried within a lumen of pushing tube 1330. Pushing tube 1330 is carried within a lumen of delivery tube 1320. Pushing tube 1330 abuts a proximal edge of extendible member 120 and is configured to apply an axial force to extendible member 120. Holding tube 1340 abuts a proximal edge of the tubular member 110 and is configured to exert axial pressure to the tubular member.

[00059] FIG. 13 further illustrates holding cord 1350 disposed within a lumen of holding tube 1340. Holding cord 1350 is threaded through a hole 1360 of tubular member 110 and both ends are disposed external to the patient. Holding cord 1350 is configured so that the cord may be removed from the vasculature after deployment of the extendible member and prior to removal of holding tube 1340, pushing tube 1330 and delivery tube 1320. Holding cord 1350 is configured to apply an axial force to the tubular member in such a fashion as to maintain contact between holding tube 1340 and the tubular member 110. Holding cord 1350, in one embodiment, comprises a tether.

[00060] The delivery system illustrated in FIG. 13 is configured so that during delivery, the tubular member 110 is maintained in contact with the holding tube 1340 by holding cord 1350. During deployment, pushing tube 1330 exerts an axial pressure on the extendible member 120 and slides extendible member 120 over the locking mechanism 140 until a distal edge of the extendible member 120 contacts the stop member 150. A desired ratchet setting is attained by applying an axial force to the pushing tube 1330 and pushing the extendible member 120 to a distal position and controlling the holding cord 1350 pulling the tubular member 110 to a proximal position. A deployment configuration is obtained. To release axial pressure on the tubular member 110, holding cord 1350 is transected and removed from the vasculature by sliding through the

holding tube 1340. Delivery tube 1320 is then removed from the vasculature. Extendible member 120 remains in the deployment configuration upon tubular member 110 at the deployment site.

[00061] In another embodiment, the delivery system is modified for guide wire delivery. In another embodiment, the delivery tube 1320 is omitted from the device 1310.

[00062] FIG. 14 illustrates another embodiment of a delivery system 1410 in accordance with another aspect of the invention. Delivery system 1410 comprises pushing tube 1430 slidably disposed upon a pull tube 1440. The distal end of pushing tube 1430 abuts the proximal end of extendible member 120. Pull tube 1440 comprises latch fingers 1450 at a distal end of pulling tube 1440. Tubular member 110 comprises an external groove 1460 disposed proximate a proximal end of tubular member 110. Latch fingers 1450 are normally splayed open, but during delivery of the delivery system 1410, latch fingers 1450 are engaged in the external groove 1460 and maintained disposed within the external groove 1460 by the push tube 1430. Latch fingers 1450 allow tension or pulling on the tubular member 110 when the pushing tube 1430 pushes the extendible member 120 to a deployment configuration. In one embodiment, latch fingers 1450 comprise a shape-memory material. Upon attaining the desired deployment configuration, the pushing tube 1430 is pulled back from its distal position, and exposes the latch fingers 1450. As latch fingers 1450 are no longer restrained within the external groove 1460, latch fingers 1450 splay open and disengage from external groove 1460. With latch fingers 1450 disengaged from external groove 1460, the entire delivery system 1410 may be removed from the vasculature. FIG. 14A illustrates the delivery system 1410 prior to disengagement, and FIG. 14B illustrates the system after disengagement prior to removal from the vasculature.

[00063] The device illustrated in FIGS. 6-8 is delivered to the desired location, and the extendible member 120 and tubular member 110 are to remain deployed at the delivery site after the end of the deployment procedure. FIG. 15 illustrates one embodiment of a delivery device 1510 configured to deliver the

device of FIGS. 6-8 through the vasculature, deploy the extendible member, and be withdrawn through the vasculature.

[00064] As illustrated in FIG. 15A, delivery device 1510 comprises delivery catheter 1520 attached to inner tube 528. FIG. 15A further illustrates slot 538 in sleeve member 518. In the embodiment illustrated in FIG. 15A, the inner tube 528 comprises a threaded attachment 560 at a proximal end, mated with a threaded receptor in the delivery catheter 1520. Alternatively, the attachment and receptor may be reversed, so that the threaded attachment 560 is disposed upon the delivery catheter and the threaded receptor is disposed within the inner tube 528. The threaded receptor and attachment 560 are configured to require a predetermined level of torque to disengage the threaded attachment. The predetermined level of torque is determined to require a higher level of torque to disengage the inner tube 528 from the sleeve member 518, than the level of torque required to rotate the sleeve member 518 to deploy the extendible member through slot 538. Alternatively, the torque may be reversed to reverse the connection and unscrew the inner tube 528 from the delivery catheter 1520.

[00065] Those of ordinary skill in the art will readily recognize that the delivery catheter 1520 must withstand torsional forces and transmit those torsional forces. In one embodiment, delivery catheter 1520 comprises a reinforcing structure. In another embodiment, delivery catheter 1520 comprises a filamentous braid.

[00066] FIG. 15B illustrates the device illustrated in FIG. 15A partially disposed within a driving catheter 1515 prior to deployment. Driving catheter 1515 is rotatably disposed around delivery catheter 1520 and comprises a key way 1570 at a distal end. Flat spring 612 includes a proximal end 529. Prior to deployment, the proximal end 529 of flat spring 612 is disposed within the key way 1570. Prior to deployment, flat spring 612 is in its restrained configuration and proximal end 529 abuts an interior wall of key way 1570.

[00067] FIG. 15C illustrates the device of FIG. 15A after deployment, wherein proximal end 529 is disengaged from driving catheter 1515. As

illustrated in FIG. 15C, flat spring 612 has extended through the slot 538 to assume its deployment configuration. Because flat spring 612 is in its deployment configuration, the proximal end 529 has pulled away from the wall of the key way 1570, and the proximal end 529 is no longer disposed within the key way 1570. To removed delivery catheter 1520 is removed from inner tub e528 as described above, and can be withdrawn with driving catheter 1515, leaving the system deployed in the coronary sinus.

[00068] Variations and alterations in the design, manufacture and use of the system and method are apparent to one skilled in the art, and may be made without departing from the spirit and scope of the present invention. While the embodiments of the invention disclosed herein are presently considered to be preferred, various changes and modifications can be made without departing from the spirit and scope of the invention. The scope of the invention is indicated in the appended claims, and all changes that come within the meaning and range of equivalents are intended to be embraced therein.

WHAT IS CLAIMED IS:

1. A system for treating cardiac valve regurgitation, comprising:

a tubular member including a locking mechanism; and

an extendible member carried on the tubular member, wherein the extendible member is movable to a deployment position responsive to application of an axial force and is locked in the deployment position with the locking mechanism.

2. The system of claim 1 wherein the locking mechanism comprises a stop member spaced apart from at least one lock member along a length of the tubular member.

3. The system of claim 2 wherein the lock member comprises a one-way protrusion lock member.

4. The system of claim 1 wherein the axial force comprises a compressive force.

5. The system of claim 1 wherein the extendible member comprises a shape memory material.

6. The system of claim 5 wherein the shape memory material is selected from the group consisting of stainless steel, nitinol, tantalum, MP35N cobalt alloy, platinum, titanium, a thermoset plastic, a suitable biocompatible alloy, a suitable biocompatible material, or a combination thereof.

7. The system of claim 1 wherein the deployment position comprises one of a single radial extended portion or a plurality of radial extending portions.

8. The system of claim 1 wherein the extendible member comprises a stent.

9. The system of claim 1, wherein the extendible member comprises one of a self-expanding stent and a balloon expanding stent.

10. The system of claim 9 wherein the balloon applies a compressive force to the cardiac valve.

11. A system for treating cardiac valve regurgitation, comprising:

a tubular member;

an extendible member carried on the tubular member; and

a sleeve member including a slot formed therein positioned over the extendible member; wherein the sleeve member is rotatable to align the slot with the extendible member.

12. The system of claim 11 wherein the extendible member comprises a self-expanding member having a predetermined deployment shape to interface with an interior wall of a vessel.

13. The system of claim 12 wherein the self-expanding member comprises a shape memory material.

14. The system of claim 13 wherein the shape memory material comprises at least one of the group consisting of stainless steel, nitinol, tantalum, MP35N cobalt alloy, platinum, titanium, a thermoset plastic, a suitable biocompatible alloy, a suitable biocompatible material, or a combination thereof.

15. The system of claim 11 wherein the extendible member comprises a balloon-expansion device having a predetermined deployment shape to interface with an interior wall of a vessel.

16. The system of claim 11 wherein the extendible member applies a compressive force to the cardiac valve when aligned with the slot.

17. A method for treating mitral valve regurgitation, the method comprising:

positioning an extendible member adjacent a cardiac valve exterior to a heart chamber via a tubular member;

applying an axial force to the extendible member;

positioning the extendible member in an extended position responsive to the axial force; and

locking the extendible member in the extended position to apply a compressive force to the cardiac valve.

18. The method of claim 17 wherein the extendible member is movable to a deployment position responsive to axial force and is locked in the deployment position with the locking mechanism.

19. The method of claim 17 wherein positioning the extendible member in an extended position comprises positioning the extendible member in one of a single radial extended portion or a plurality of radial extending portions.

20. A method for treating mitral valve regurgitation, the method comprising:

positioning an extendible member adjacent a cardiac valve exterior to a heart chamber via a tubular member;

applying a rotational force to a sleeve member positioned on the extendible member;

aligning a slot of the sleeve member with the extendible member responsive to the rotation; and

deploying the extendible member through the slot and adjacent the cardiac valve.

21. The method of claim 20 wherein deploying the extendible member applies a compressive force to the mitral valve.

CORONARY SINUS APPROACH FOR REPAIR
OF MITRAL VALVE REGURGITATION

ABSTRACT OF THE DISCLOSURE

The invention provides a device and method for treating cardiac valve regurgitation. The device includes a tubular member (110) including a locking mechanism (140, 150) and an extendible member (120) carried on the tubular member (110). The extendible member (120) is moveable to a deployment configuration (S1110) in response to an axial force (S1120) and locked in the deployment configuration by the locking mechanism (S1140). The invention also provides a device including a tubular member (110), extendible member (120) carried on the tubular member and a sleeve member (518). The sleeve member (518) includes a slot (538), and is rotatable to align the extendible member (120) with the slot (538). One method includes positioning the extendible member adjacent a cardiac valve (S1110) and applying an axial force (S1120) to the extendible member to position the extendible member in a deployment configuration (S1130), and locking the extendible member in the deployment configuration (S1140) and applying a compressive force to the cardiac valve.

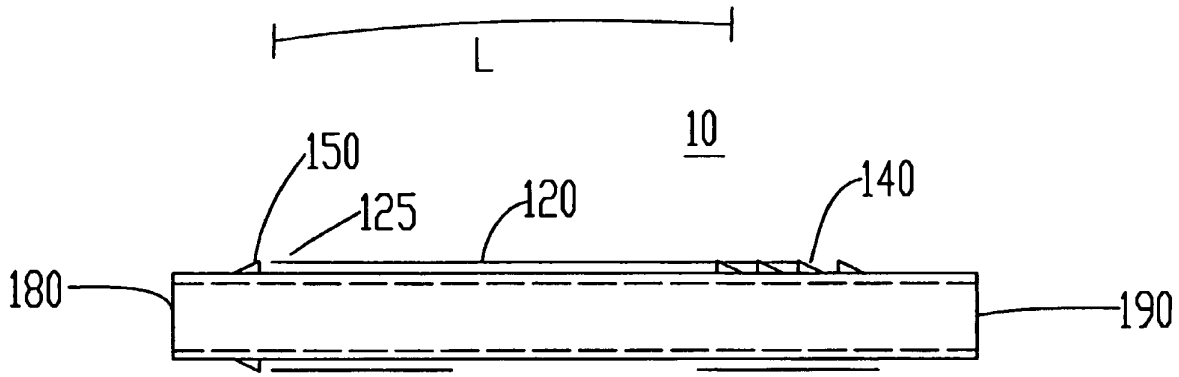

FIG. 1

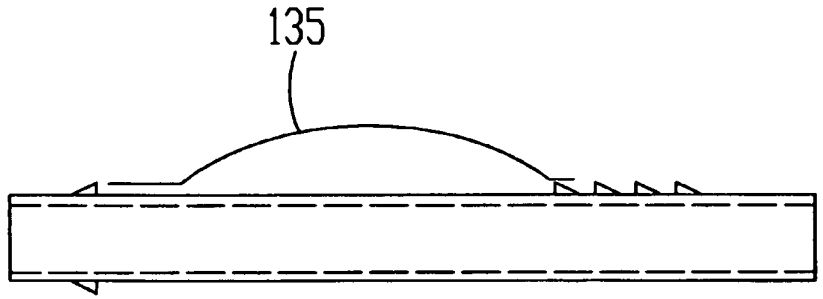

FIG. 2

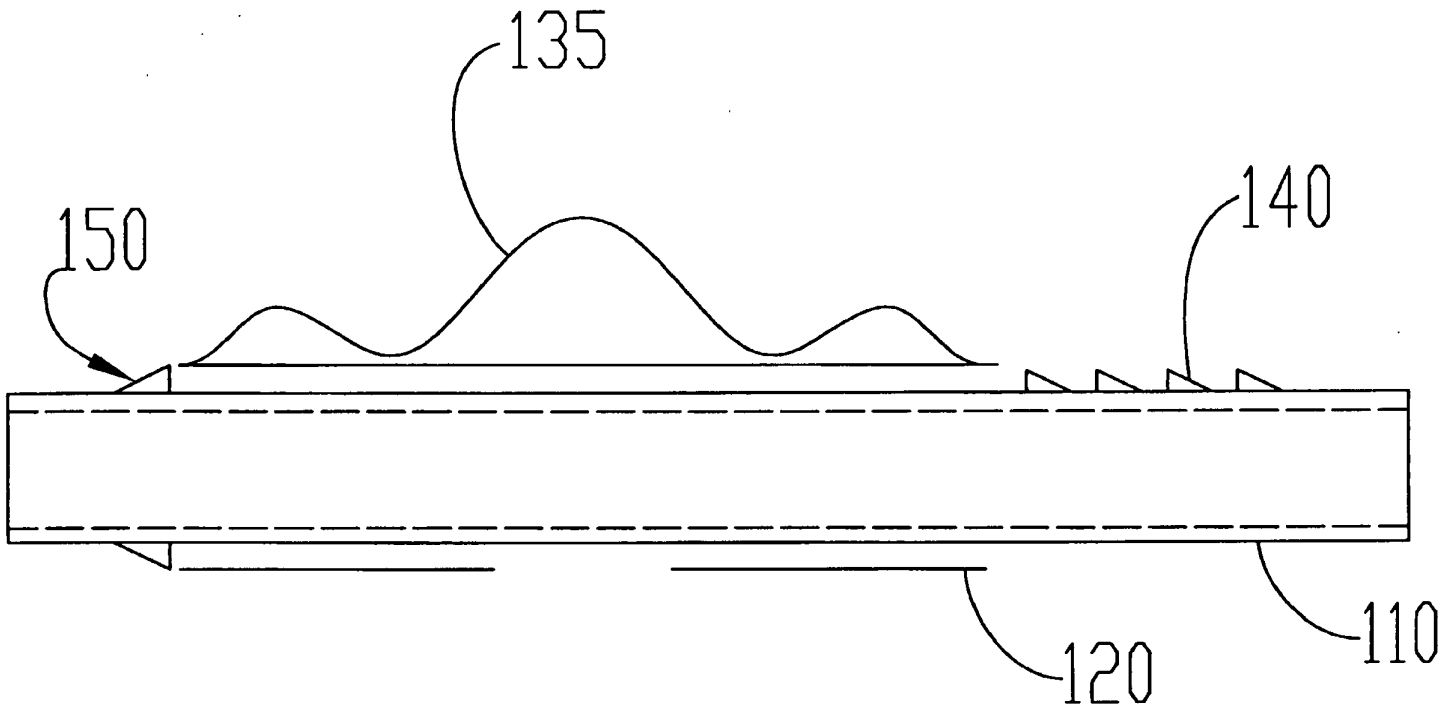

FIG. 3

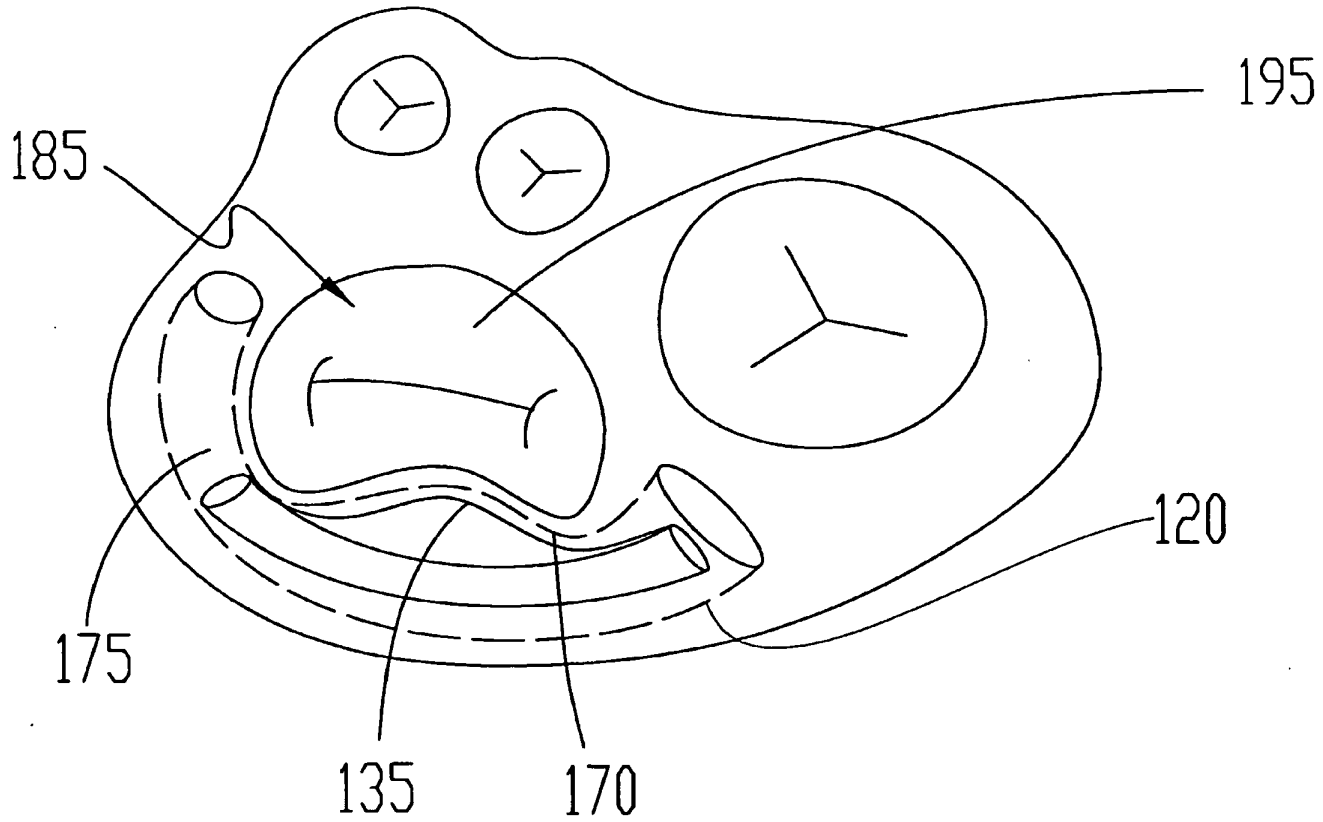

FIG. 4

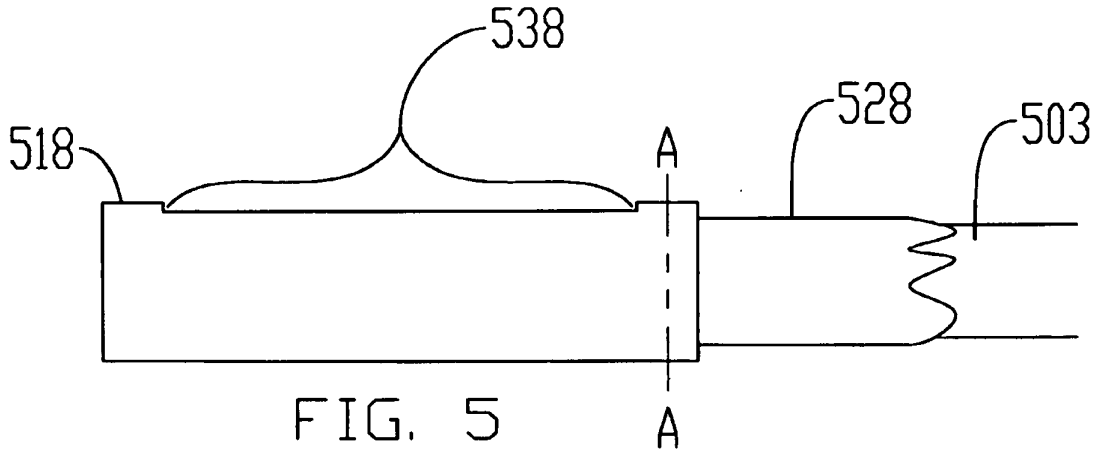

FIG. 5

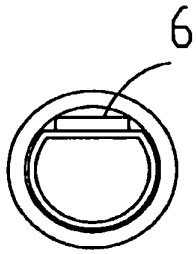

FIG. 6

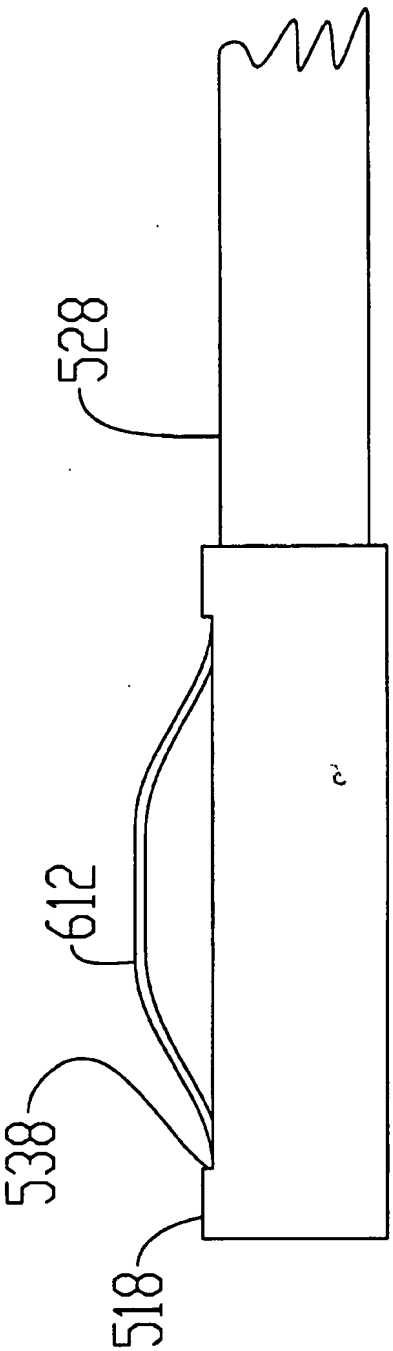

FIG. 7

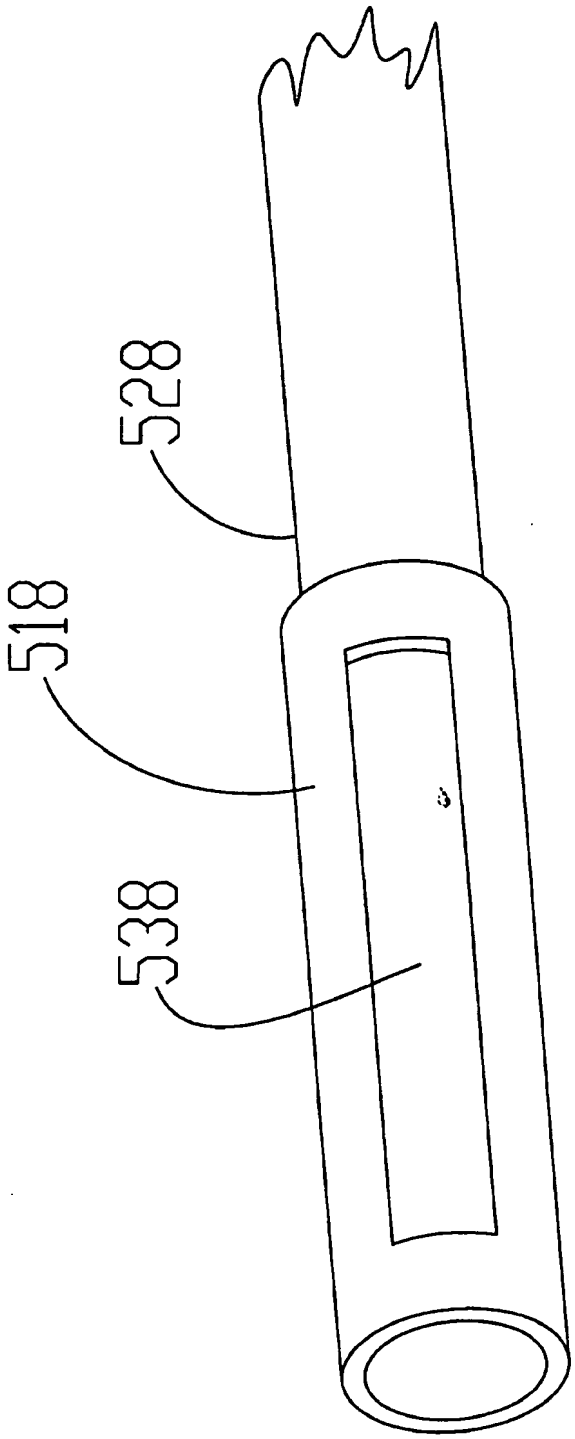

FIG. 8

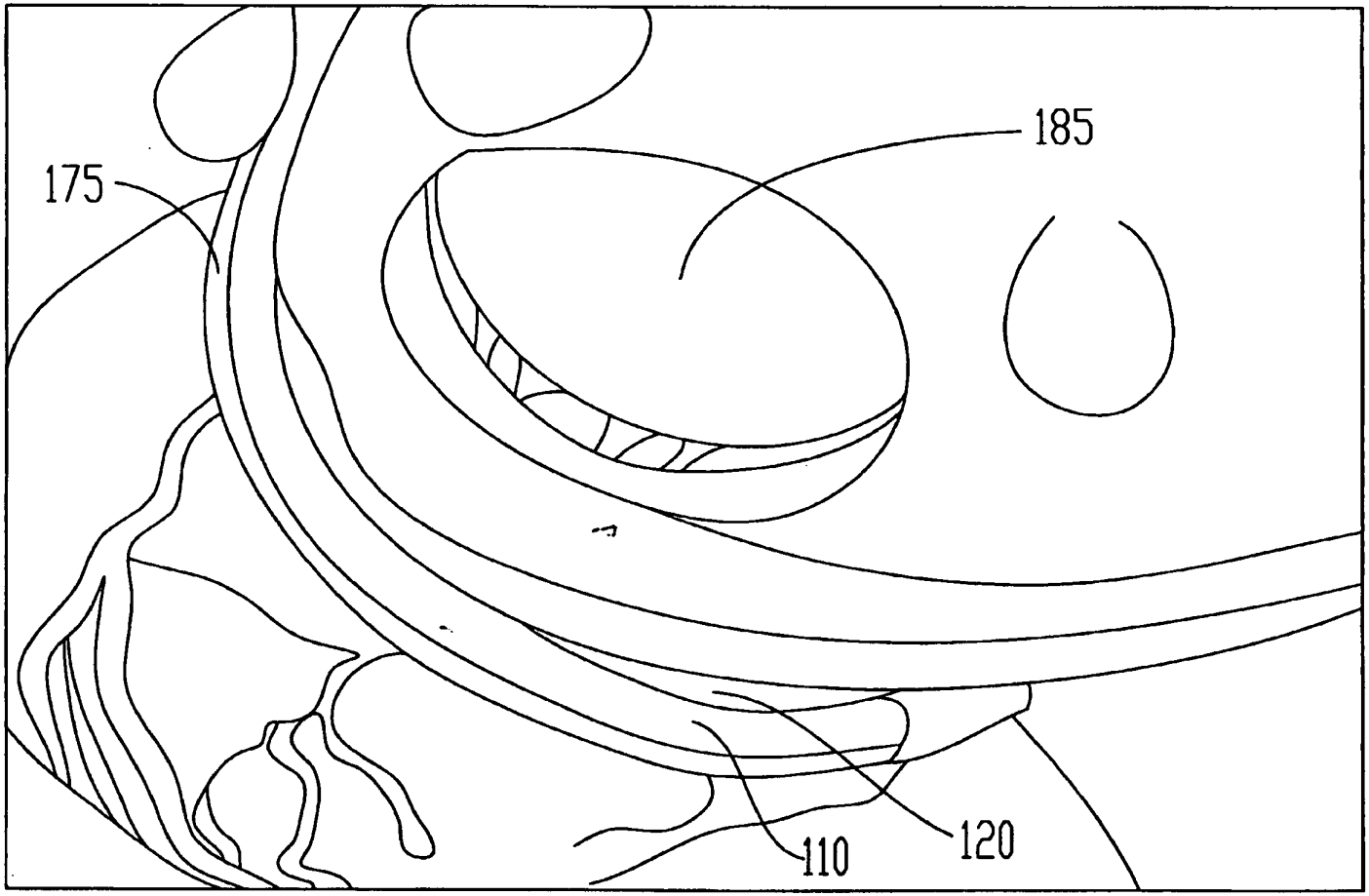

FIG. 9

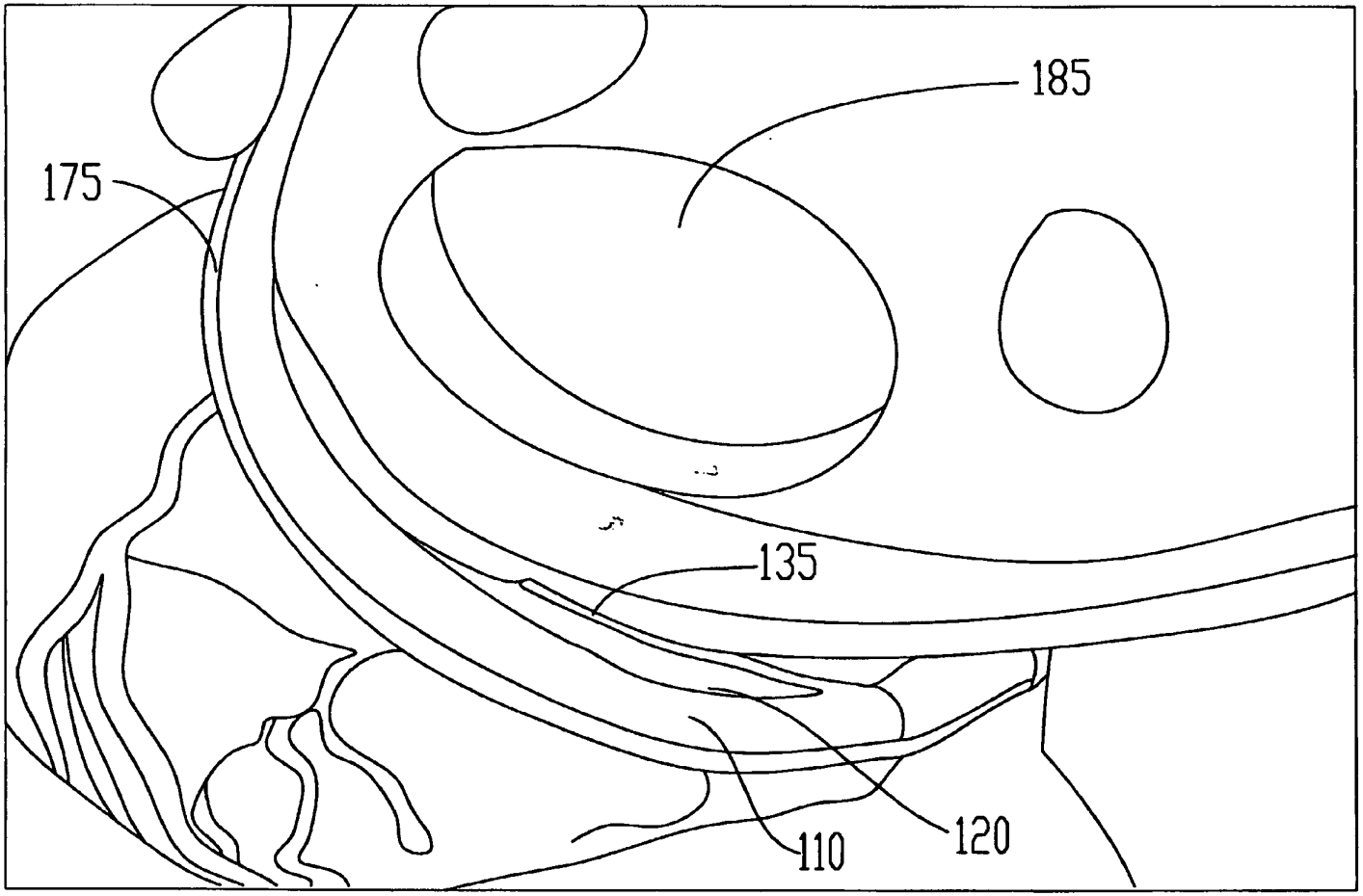

FIG. 10

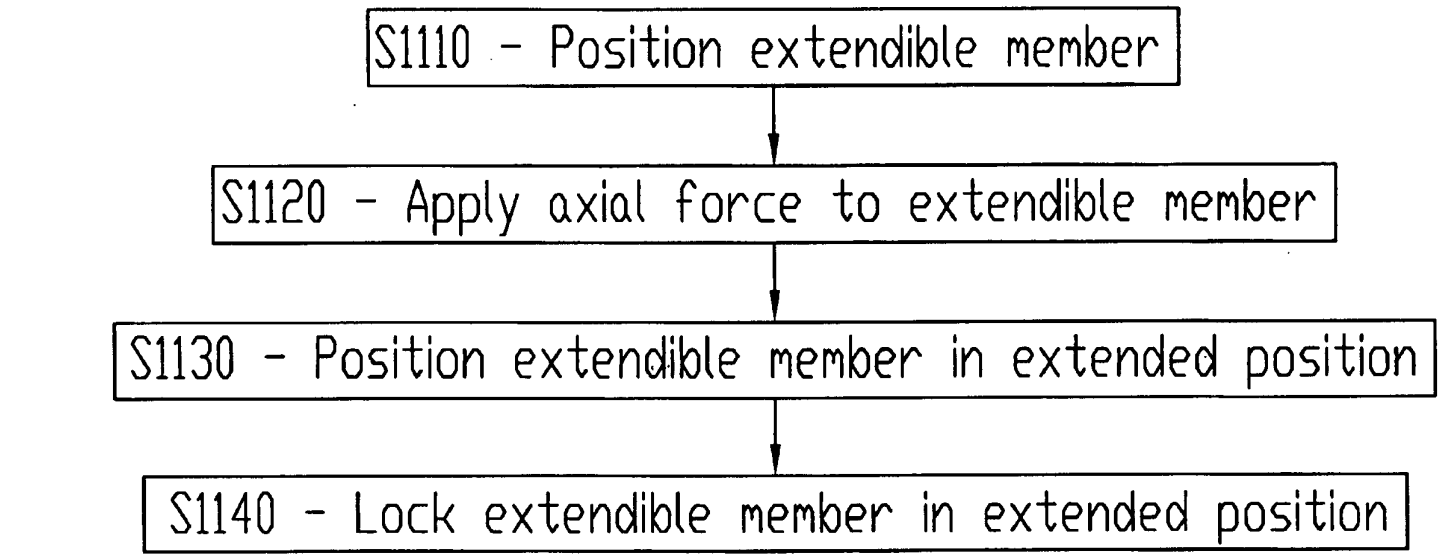
1100
S1110 - Position extendible member
S1120 - Apply axial force to extendible member
S1130 - Position extendible member in extended position
S1140 - Lock extendible member in extended position

FIG. 11

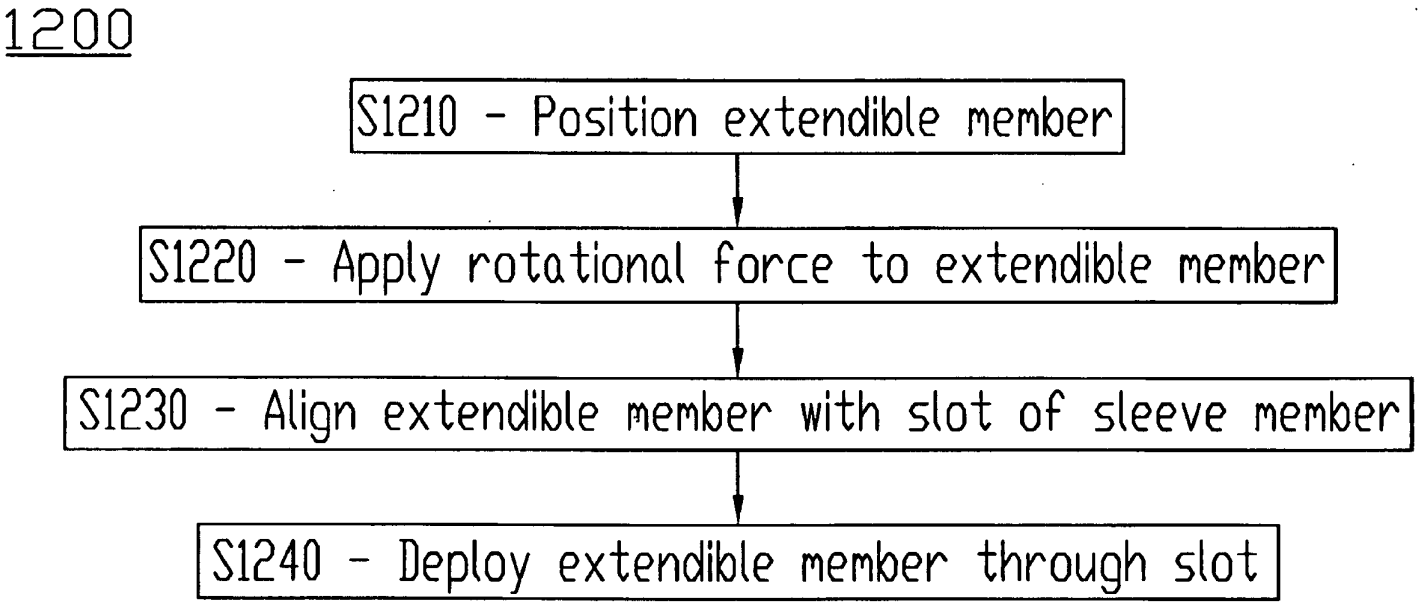
1200
S1210 - Position extendible member
S1220 - Apply rotational force to extendible member
S1230 - Align extendible member with slot of sleeve member
S1240 - Deploy extendible member through slot

FIG. 12

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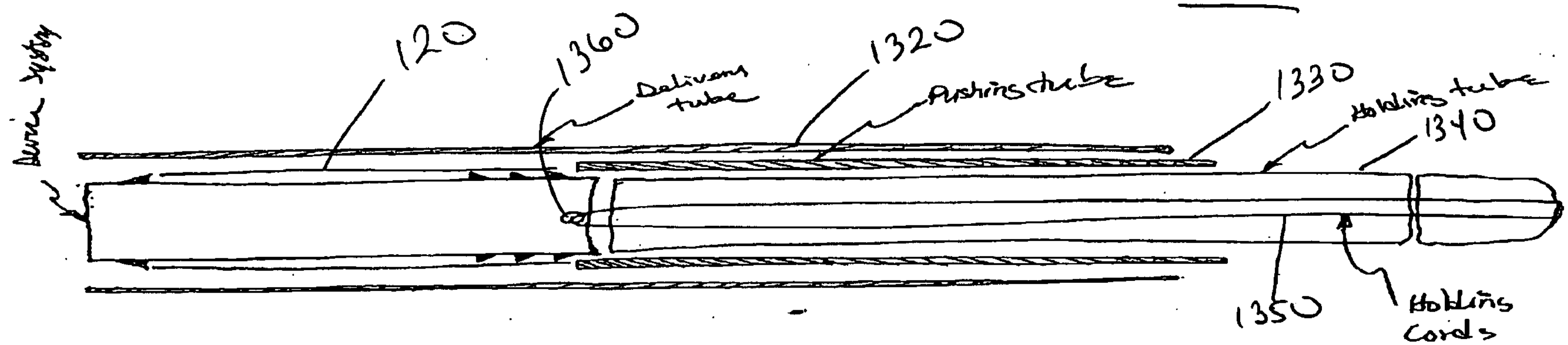

note: When after the device positioned in place, the Holding Cords proximal end is cut and the holding tube and holding cords is removed. Then the Push tube and delivery tube are removed

FIG. 13

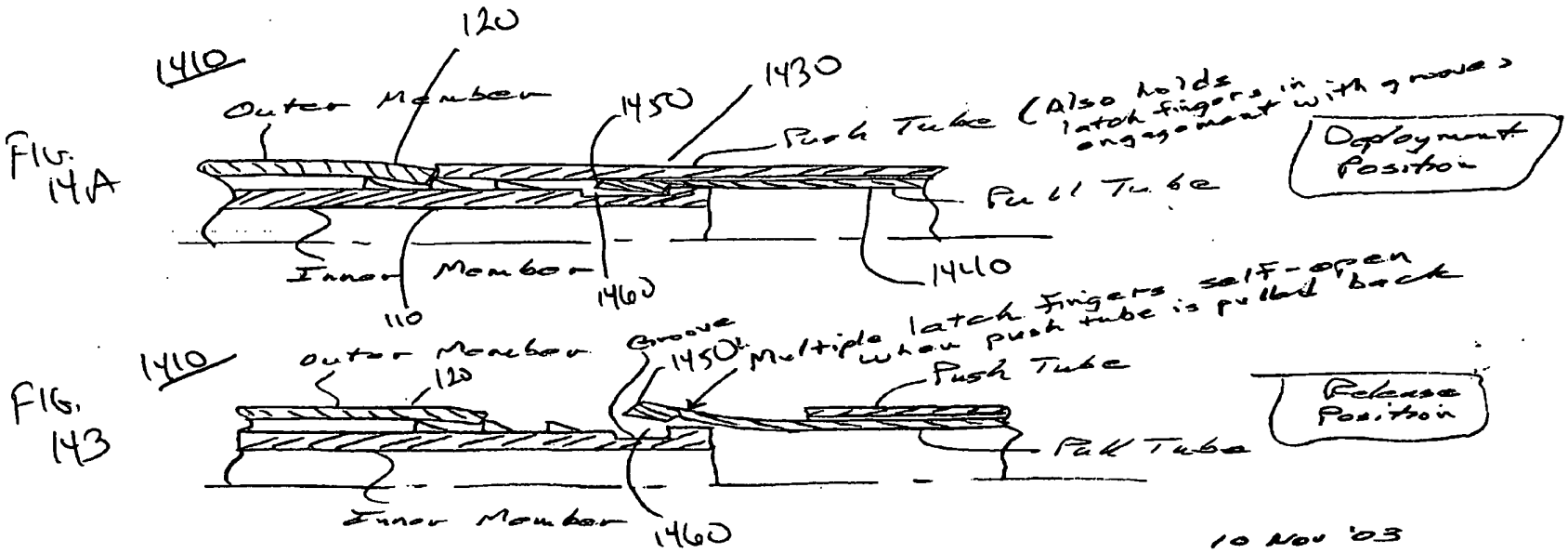

FIG. 14A

FIG. 14B

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10 Nov '03
J. Gutierrez

FIG 15A

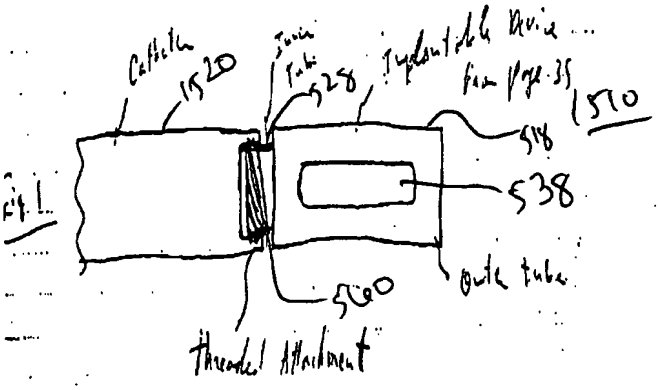


Fig. 1

FIG 15B

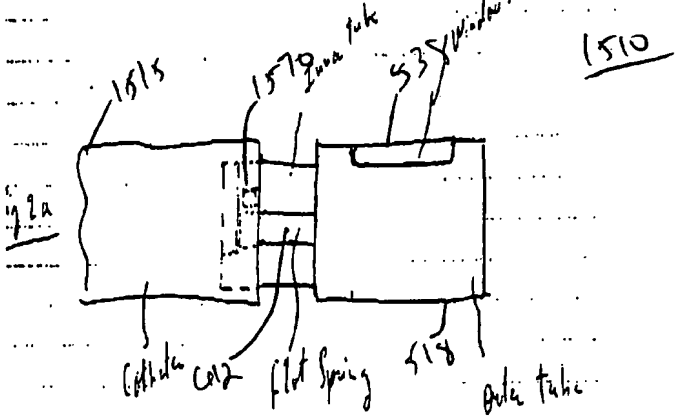
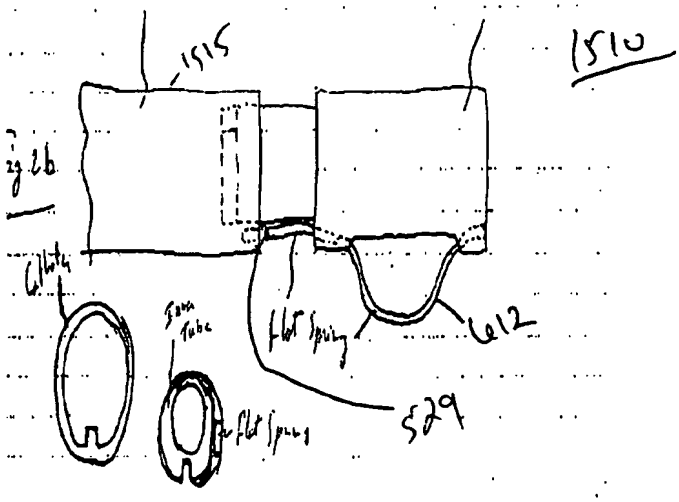


FIG 15C



Witnessed & Understood by me. David Brown Date 11-10-03 Invented by [illegible] Date 11-10-03 Recorded by [illegible]